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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,792	08/08/2006	Massimo Bani	PB60734USW	6405
23347 7590 06/19/2008 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER FRAZIER, BARBARA S				
ART UNIT 1611		PAPER NUMBER		
NOTIFICATION DATE 06/19/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/597,792

Applicant(s)

BANI, MASSIMO

Examiner

BARBARA FRAZIER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 7-9 are pending in this application. Addition of new claim 9 is acknowledged.
2. Claims 1-6 stand canceled.
3. Claims 7-9 are examined.

Claim Rejections - 35 USC § 112

4. The rejection of claims 5, 7, and 8 under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicant's amendment canceling the phrase "or solvate".

Claim Rejections - 35 USC § 102

5. The rejection of claims 5, 7, and 8 under 35 U.S.C. 102(a) as being anticipated by Melotto (WO 2004/091617) is withdrawn in view of Applicant's arguments that the foreign priority date of the instant application is before the publication date of Melotto '617.
6. The rejection of claims 5, 7, and 8 under 35 U.S.C. 102(e) as being anticipated by Melotto (WO 2004/091617) is withdrawn in view of Applicant's arguments that the foreign priority date of the instant application is before the filing date of Melotto '617.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armour et al (WO 95/08549) in view of Carlson et al (US Patent 6,117,855).**

The claimed invention is drawn to a method of treatment of social phobia which comprises administering to a human in need thereof an effective amount of [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-([2S,3S]-2-phenyl-piperidin-3-yl) amine or a pharmaceutically acceptable salt thereof (see claim 8). A specific salt is the dihydrochloride salt (see claims 7 and 9).

Armour et al teach 3-(5-tetrazolyl-benzyl)amino-piperidine derivatives (abstract). The compounds are potent and specific NK₁ antagonists (page 10, line 9). A preferred compound is [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-(2S-phenyl-piperidin-3S-yl) amine, and pharmaceutically acceptable salts, especially the dihydrochloride

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salts (page 8, lines 24-29). The compounds may be useful in the treatment of CNS disorders, in particular psychoses such as anxiety (page 11, lines 8-10).

Armour et al do not specifically teach that the anxiety disorder to be treated is social phobia.

Carlson et al. generally teach that, when NK-1 receptor antagonists are used to treat anxiety, the term "anxiety" includes specific phobias such as social phobia (col. 4, lines 37-44).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the compound as taught by Armour et al to treat social phobia; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because Armour et al fairly suggests the use of [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-(2S-phenyl-piperidin-3S-yl) amine or its salt for the treatment of anxiety, such that one skilled in the art would reasonably expect the NK1 antagonists to be useful in the treatment of anxiety. Additionally, Carlson et al teach that the term "anxiety" includes social phobia when using NK-1 receptor antagonists to treat anxiety. One would reasonably expect success from the use of [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-([2S,3S]-2-phenyl-piperidin-3-yl) amine to treat an anxiety disorder as taught by Armour et al wherein the anxiety disorder is social phobia as taught by Carlson et al because both references are drawn to the use of NK1 antagonists to treat anxiety.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 7-9 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 19 and 20

of copending Application No. 10/552,870. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same subject matter and composition components.

The instant application claims a method of treatment of social phobia which comprises administering to a human in need thereof an effective amount of [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-([2S,3S]-2-phenyl-piperidin-3-yl) amine or a pharmaceutically acceptable salt thereof (see claim 8). A specific salt is the dihydrochloride salt (see claims 7 and 9).

Copending application '870 claims a method for the treatment of anxiety comprising administering a therapeutically effective combination of [2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)]-([2S,3S]-2-phenyl-piperidin-3-yl) amine or a pharmaceutically acceptable salt thereof and paroxetine or a salt thereof (claim 19).

Copending application '870 does not specifically teach a method for the treatment of social phobia, and also includes the additional agent paroxetine. However, one skilled in the art would understand "anxiety" to include social phobia, based on the definition of "anxiety" given in the parent international application of application '870 (see WO 2004/91617, page 7, lines 28 and 32). Furthermore, Applicant's open-ended term "comprising" allows for the presence of additional agents, including paroxetine. Additionally, the phrase "an effective amount" in claim 8 of the instant application is not limited to certain dosage range, but can include dosage ranges where additional active agents, such as paroxetine, are present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant's Remarks

12. Applicant's arguments filed 3/31/08 have been fully considered but they are not persuasive.

Applicants argue that "It is the Office's practice to issue a restriction between claims to methods of treatment utilizing a claimed compound and claims to methods of treatment utilizing a combination of the compound with another active agent. The Office has on many instances taken the position that such claims are drawn to patentably

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distinct inventions and have required and garnered substantial additional fees for divisional applications necessitated by such restriction".

This argument is not persuasive. No restriction has been made in either the instant application or copending application '870. The facts of the instant case shall be limited to those applications currently under consideration (i.e., the instant application and copending application '870), and not other applications before the Office. In the instant case, the claims are drawn to the same subject matter and composition components, for the reasons of record (see above).

Applicants then argue that the Examiner provides no rationale to support the conclusion that the claimed inventions would be obvious one over the other. Applicants also argue that the fact that both methods are drawn to methods of treatment does not support the Examiner's conclusion that the instantly claimed methods of treatment would render obvious treatment with a combination.

This argument is not persuasive because the claims of the instant application are not limited to a method of treatment consisting of a single agent, but rather are a method of treatment **comprising** the compound claimed in claim 8. Applicant's open-ended term "comprising" allows for the presence of additional agents, including paroxetine, as claimed in claim 19 of copending application '870.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is

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(571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615

BSF